



Structured Product Labeling (SPL)

Preparing for FDA Electronic Drug Registration and Drug Listing

October 29-30, 2008 | Sheraton Philadelphia City Center Hotel, Philadelphia, PA, USA

PROGRAM CHAIRS

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Reed Technology and Information Services Inc.

WHO SHOULD ATTEND

Professionals responsible for registering drug establishments and listing drug products, as well as individuals and organizations responsible for developing and maintaining software designed to produce SPL for submission to FDA who work in/with:

- ▶ Regulatory Affairs
- ▶ Biotechnology
- ▶ Chemistry & Manufacturing Controls
- ▶ Dictionaries/Data Standards
- ▶ Document Management
- ▶ Generics
- ▶ Information Management
- ▶ Information Technology
- ▶ Manufacturing: Drug Substance, Drug Product, Packaging
- ▶ Over-the-counter Drugs
- ▶ Research & Development/Strategic Issues
- ▶ Veterinary Companies

Learn How to Register Your Drug Establishments and List Your Drug Products Now, Before It's Too Late!

The FDA Amendments Act placed into law the requirement for electronic drug establishment registration and drug listing. FDA is adopting the use of extensible markup language (XML) files in a standard SPL format as the standard format for the exchange of drug establishment registration and drug listing information.

KEY TOPICS

- Electronic drug establishment registration and listing SPL
- Data Universal Numbering System (D-U-N-S®)
- Electronic Submissions Gateway (ESG)
- SPL reference documents
- SPL lifecycle management
- Listing data elements/Terminology
- Transitioning from paper to electronic

SPECIAL PANEL DISCUSSIONS

- Animal drugs
- Active Pharmaceutical Ingredients (APIs)
- Brand names
- Biologics
- Generics
- Over-the-counter drugs (OTC)

We want to know: What do YOU want to know?

FDA representatives will be on hand to answer your specific questions and requests for clarification on preparing for Electronic Drug Registration and Drug Listing in SPL. So that these representatives can properly prepare for this Question & Answer period, we request that registrants submit their questions prior to the conference. Please submit your questions to 2008SPLconference@diahome.org.

All questions will be forwarded to the FDA anonymously. Questions will be accepted until 5PM EDT, October 24, 2008.

SPL VENDOR SHOWCASE

This SPL conference will include a special presentation titled SPL Vendor Showcase. The SPL Vendor Showcase provides a fantastic opportunity for attendees to evaluate a number of currently available services and tools as they are used to produce an equivalent final product. During this session, each participating vendor will be allocated time to demonstrate their services and/or tool and present their results.

**SPECIAL
EVENT**

LEARNING OBJECTIVES At the conclusion of this meeting, participants should be able to:

- ▶ Identify information to be included in electronic drug establishment registration and drug listing submissions;
- ▶ Discuss the nuances of SPL lifecycle management; and
- ▶ Explain SPL Release 4 terminology.

**Special SPL
Webinar!**

Get a primer on SPL Implementation during DIA's webinar
Structured Product Labeling (SPL) Implementation

September 9

11:00 AM-2:00 PM EDT

Register today at www.diahome.org.

CONTACT INFORMATION

Conference: Ben Zaitz, Phone +1-215-293-5803/email Benjamin.Zaitz@diahome.org

Exhibits: Erin Gilliland, Phone +1-215-442-6149/email Erin.Gilliland@diahome.org

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

TRAVEL AND HOTEL The most convenient airport is Philadelphia International Airport and attendees should make airline reservations as early as possible to ensure availability. The Sheraton Philadelphia City Center Hotel is holding a block of rooms at the reduced rate below until September 28, 2008, for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Single \$239 Double \$259

Please contact the Sheraton Philadelphia City Center Hotel by telephone at +1-215-448-2000 and mention the DIA event. The hotel is located at 17th and Race Streets, Philadelphia, PA 19103, USA.

Participants with Disabilities

DIA event facilities and overnight accommodations are accessible to persons with disabilities. Services will be made available to sensory-impaired persons attending the event if requested at least 15 days prior to event. Contact the DIA office to indicate your needs.

CANCELLATION POLICY: On or before OCTOBER 23, 2008

Administrative fee that will be withheld from refund amount: Member/Nonmember = \$200 • Government/Academia/Nonprofit (Member/Nonmember) = \$100

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

PLEASE CONSIDER THIS FORM AN INVOICE

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Meeting I.D. # 08029 – October 29-30, 2008

Sheraton Philadelphia City Center Hotel, Philadelphia, PA, USA

Registration Fees

If DIA cannot verify your membership upon receipt of registration form, you will be charged the nonmember fee. Registration fee includes refreshment breaks, luncheons and reception and will be accepted by mail, fax, or online.

MEMBER EARLY-BIRD OPPORTUNITY

Available on nondiscount member fee only.

Member Fee

	On or before OCT. 8, 2008	After OCT. 8, 2008
Member Fee	US \$1200 <input type="checkbox"/>	US \$1380 <input type="checkbox"/>

Join DIA now to qualify for the early-bird member fee! www.diahome.org/en/Membership/AboutMembership/AboutMembership

MEMBERSHIP
US \$ 130 ☐

To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

Nonmember Fee

US \$1510 ☐

A one-year membership to DIA is available to those paying a NONMEMBER registration fee. If paying a nonmember fee, please indicate if you do, or do not, want membership.

I want to be a DIA member ☐

I do NOT want to be a DIA member ☐

Discount Fees

MEMBER

NONMEMBER*

Government (Full-time)

US \$ 350 ☐

US \$ 480 ☐

Charitable Nonprofit/Academia (Full-time)

US \$ 695 ☐

US \$ 825 ☐

*If paying a nonmember fee, please check one box above, indicating whether you want membership.

☐ To receive a tabletop exhibit application, please check.

CONTACT & TABLETOP EXHIBIT INFORMATION Attendees may visit the tabletop exhibits during the event and receptions.

Event information: Contact Ben Zaitz at the DIA office by telephone +1-215-293-5803, fax +1-215-442-6199 or email benjamin.zaitz@diahome.org.

Tabletop exhibit information: Contact Erin Gilliland, Exhibits Associate, at the DIA office by telephone +1-215-442-6149, fax +1-215-442-6199 or email Erin.Gilliland@diahome.org. For tabletop exhibit space, please check the box in the registration area below.

PAYMENT REGISTER ONLINE AT www.diahome.org or please check payment method:

☐ **CHECK** drawn on a US bank payable to and mailed along with this form to: Drug Information Association Inc, P.O. Box 95000-1240, Philadelphia, PA 19195-1240, USA. Please include a copy of this registration form to facilitate identification of attendee.

☐ **CREDIT CARD** number may be faxed to: +1-215-442-6199. You may prefer to pay by check or bank transfer since non-U.S. credit card payment will be subject to the currency conversion rate at the time of the charge.

☐ Visa ☐ MC ☐ AMEX Expiration Date _____

Card # _____

Signature _____

☐ **BANK TRANSFER** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the Bank Transfer. Payment should be made in US dollars. Your name and company, as well as the Event I.D. # must be included on the transfer document to ensure payment to your account.

GROUP DISCOUNTS* Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must register and prepay at the same time – no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

☐ Please indicate that this form is part of a group registration by checking this box.

Please list below the names of the other three registrants from your company.

1. _____
2. _____
3. _____

Please complete the information below.

Please check the applicable category: ☐ Academia ☐ Government ☐ Industry ☐ CSO ☐ Student (Call for registration information)

Last Name _____ First Name _____ M.I. _____ Degrees _____ ☐ Dr. ☐ Mr. ☐ Ms.

Job Title _____ Affiliation (Company) _____

Address (Please write your address in the format required for delivery to your country.) _____ City _____ State _____ Zip _____ Country _____

email (Required for confirmation.) _____ Telephone Number _____ Fax Number (Required for confirmation.) _____

☐ I cannot attend but please keep me informed of DIA's future events.